

DEPARTMENT OF AGRICULTURE
FOOD DIVISION
REGULATION NO. 569. SMOKED FISH

(By authority conferred on the department of agriculture by section 23 of Act No. 39 of the Public Acts of 1968, as amended, being §289.723 of the Michigan Compiled Laws)

R 285.569.1 Definitions.

Rule 1. (1) As used in these rules:

(a) "Cold process smoked fish" means a smoked fish that has not been subjected to sufficient heat to coagulate the protein throughout the fish.

(b) "Critical control point" means a point, step, or procedure in a food process at which control can be applied and as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

(c) "Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

(d) "Fish" means all freshwater or saltwater finfish, mollusks, crustaceans, and other aquatic organisms, other than birds or mammals, that are intended for human consumption.

(e) "Fish product" means any article of food or any other article intended for, or capable of being used as, human food that is derived or prepared, in whole or in part, from any portion of any fish.

(f) "Hazard analysis and critical control point (HACCP) plan" means a food processing plan under which a food processing plant operator effectively prevents food safety hazards by monitoring food safety variables at critical control points and by controlling the variables within critical limits.

(g) "Hot process smoked fish" means a smoked fish that has been subjected to sufficient heat for a sufficient period of time to coagulate the protein throughout the fish.

(h) "Liquid smoke" means an aqueous solution of wood smoke that, when suitably diluted, may be used to impart a smoke flavor.

(i) "Loin muscle" means the longitudinal quarter of the great lateral muscle of the fish that is free from skin, scales, visible blood clots, bones, gills, and nonstriated parts.

(j) "Process authority" means a person who has expert knowledge of the commercial processing of fish and fishery products based on a combination of education, training, and experience.

(k) "Reduced oxygen packaging" means packaging that reduces the amount of oxygen in a package by mechanical evacuation of the oxygen, displacing the oxygen with another gas or combination of gases, or otherwise controlling the oxygen content in a package to a level below the level of 21% normally found in the surrounding atmosphere. "Reduced oxygen packaging" includes altered atmosphere, modified atmosphere, controlled atmosphere, low oxygen and vacuum packaging.

(l) "Smoked fish" means a freshwater or saltwater finfish that is prepared by treating it with salt (sodium chloride) and subjecting it to the direct action of the smoke from burning wood, wood sawdust, or similar burning material or from liquid smoke flavoring applied to the surface in a gaseous, liquid, or vaporized state with or without heat. The term includes products composed in whole or in part from smoked fish, such as sausage, pâte, or snack dip.

(m) "Temperature-indicating device" means an accurate, standard thermometer or equivalent device, such as a resistance temperature device or thermocouple.

(n) "Temperature-recording device" means a device that is capable of providing a continuous record of the temperature conditions being monitored.

(o) "Water phase salt" means the percentage of salt (sodium chloride) in the water phase of the finished fish product. It is calculated by multiplying the percentage of salt (sodium chloride) by 100 and dividing that number by the sum of the percentage of salt (sodium chloride) and the percentage of moisture in the finished product. Moisture and salt content shall be determined in accordance with the method described in the publication entitled "Official Methods of Analysis of AOAC, International" 16th edition. The publication is adopted in these rules by reference and may be obtained from AOAC, International, 2200 Wilson Boulevard, Suite 400-GG, Arlington, Virginia 22207-3301, at a cost as of the time of adoption of these rates of \$359.00 (print version), or from the Department of Agriculture, Food Division, Ottawa Building, Fourth Floor, P.O. Box 30017, Lansing, MI 48909, at cost.

(2) Terms defined in Act No. 39 of the Public Acts of 1968, as amended, being §289.701 et seq. of the Michigan Compiled Laws, have the same meanings when used in these rules.

History: 1997 MR 2, Eff Feb. 21, 1997.

R 285.569.2 Exemptions from rules.

Rule 2. The following fish products are exempt from the requirements of these rules:

(a) Finnan haddie, smoked cod fillet, smoked Scottish kipper, or other smoked fish that is clearly labeled to be cooked before consumed.

(b) Boneless, smoked salted herring; smoked, dry salted herring; smoked blind robbin; or other smoked fish that has a water phase salt content of not less than 10%.

(c) Commercially sterile smoked fish, either canned or in sterile packaging.

History: 1997 MR 2, Eff Feb. 21, 1997.

R 285.569.3 Fish-smoking establishment; requirements; temperature-indicating devices and temperature-recording devices generally.

Rule 3. (1) A fish-smoking establishment shall be in compliance with the requirements of R 285.553.1 to R 285.553.26 in addition to the requirements of these rules.

(2) When reference is made to a temperature-indicating device and temperature-recording device, the following conditions shall apply:

(a) A temperature-indicating device shall be installed where it can be easily read and the sensor for the device shall be located to ensure that it accurately measures the warmest temperature of the refrigeration equipment and the coldest temperature of the smoking equipment, as appropriate. The sensor shall be protected from mechanical damage. A temperature indicating device shall be calibrated at the routine operating temperature of the refrigeration, cooling, or smoking equipment against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently if necessary to ensure its accuracy. Records of accuracy checks for a temperature-indicating device shall be maintained and shall specify the date, standard used, method used, results, and the person performing the test. A temperature-indicating device that has a divided fluid column or that cannot be adjusted to the standard shall be immediately repaired or replaced.

(b) A temperature-recording device shall be installed where it can be easily read and the sensor, for the device shall be installed to ensure that it accurately measures the warmest temperature of the refrigeration equipment and the coldest temperature of the smoking equipment, as appropriate. Each temperature-recording device shall be checked for accuracy against a known accurate temperature-indicating device upon installation and at

least once a year thereafter or more frequently if necessary to ensure its accuracy. A record of the accuracy checks shall be maintained that specifies all of the following information:

- (i) The time and date of each check
- (ii) The temperatures indicated by both devices before adjustment.
- (iii) The corrective action taken, where applicable.
- (iv) The person who performed the accuracy check.

History: 1997 MR 2, Eff Feb. 21, 1997.

R 285.569.4 Fish, fish products, and ingredients; condition; processing, handling, storing, preparing, and transporting at certain temperature required; inspection and washing before processing; thawing; evisceration.

Rule 4. (1) All fish, fish products, and ingredients shall be clean and wholesome, free from any deterioration, spoilage, adulteration, or foreign odors, and processed, handled, stored, prepared, and transported at or below 38 degrees Fahrenheit (3.3 degrees Celsius) so as to be safe for human consumption.

(2) Fresh fish received shall be inspected and adequately washed with potable water before processing. Only sound, wholesome fish that are free from adulteration and organoleptically detectable spoilage shall be processed.

(3) All fish received in a frozen state shall be either thawed promptly and processed or stored at a temperature that will maintain the fish in a frozen state. Thawing shall be carried out in as rapid a manner as possible so that the internal temperature of the fish does not exceed 38 degrees Fahrenheit (3.3 degrees Celsius). After thawing, the fish shall be adequately washed with potable water before processing.

(4) All fish destined for smoking shall be eviscerated. The evisceration of fish shall be conducted in an area that is separate from other processing operations. The evisceration shall be performed with minimal disturbance of the intestinal tract contents. Upon evisceration, the fish, including the body cavity, shall be washed thoroughly with a continuous flow or vigorous spray of potable water that may be chlorinated at safe levels.

History: 1997 MR 2, Eff Feb. 21, 1997.

R 285.569.5 Brining.

Rule 5. (1) Before smoking, fish shall be dry-salted or brined in a manner that will ensure an adequate and consistent water phase salt content of the finished product.

(2) Brining of fish for smoking shall be carried out so that the temperature of the brine does not exceed 60 degrees Fahrenheit (16 degrees Celsius) at the start of brining. If the brining time is more than 4 hours, then the brining shall take place in a refrigerated area that is at a temperature of 38 degrees Fahrenheit (3.3 degrees Celsius) or below immediately after the salting step.

(3) Brining tanks shall be cleaned and sanitized before each use. Brines shall not be reused unless there is an adequate process available to return the brine to an acceptable microbiological level.

(4) After removal from a brining solution, fish shall be rinsed with potable water.

History: 1997 MR 2, Eff Feb. 21, 1997.

R 285.569.6 Application of smoke.

Rule 6. (1) Fish to be smoked shall be arranged without overcrowding or touching each other within the smokehouse oven or chamber to allow for uniform smoke absorption, heat exposure, and dehydration. Liquid smoke, generated smoke, or a combination of liquid

smoke and generated smoke shall be applied to all surfaces of the fish. The surfaces of the fish to be smoked shall be moist or tacky to the touch at the beginning of the smoking step.

(2) If only liquid smoke or only generated smoke is used, then it shall be applied before the surface protein on the fish has been allowed to dry to the point of forming a pellicle or barrier to smoke uptake.

(3) If a combination of liquid smoke and generated smoke is used, then the liquid smoke shall be applied before the surface protein on the fish has been allowed to dry to the point of forming a pellicle or barrier to smoke uptake and the generated smoke may be applied at any stage of the process.

History: 1977 MR 2, Eff. Feb. 21, 1997.

R 285.569.7 process time and temperature; records of heat treatment.

Rule 7. (1) All smoking shall be accomplished so that the internal temperature of the coldest part of the fish remains at or above 145 degrees Fahrenheit (62.8 degrees Celsius) for not less than 30 continuous minutes. The temperature measurement shall be obtained by inserting the sensor of the temperature-recording device into the thickest flesh portion of one of the largest fish being smoked that is located at the coldest area of the smokehouse.

(2) An accurate record of the entire process time and internal temperature shall be taken for each smokehouse load.

(3) The record specified in subrule (2) of this rule shall indicate the date, including month, day, and year.

(4) Each smokehouse load shall be assigned a lot number that corresponds to, and can be easily identified with, the record of the thermal process time and temperature produced by the temperature-recording device.

(5) A record for each load shall also indicate the smokehouse or compartment number, the type or species of fish, and the quantity of fish smoked.

(6) The plant manager shall review and certify by initialing the entry for each load made on the recording chart or in the smoking record before distribution or sale of any smoked fish within the load.

History: 1997 MR 2, Eff. Feb. 21, 1997.

R 285.569.8 Finished fish product.

Rule 8. (1) Immediately after the thermal process, the smoked fish shall be cooled to a temperature of 38 degrees Fahrenheit (3.3 degrees Celsius) or below and shall remain at or below that temperature at all times, including through all storage, marketing, and sales channels. If smoked fish is to be frozen, the freezing shall occur immediately after the thermal process and cooling step, and the smoked fish shall remain frozen at all times, including through all storage, marketing, and sales channels. Each room, compartment, or holding device for the storage of smoked fish shall be equipped with an accurate temperature-indicating device. Every person responsible for handling smoked fish up to the time it reaches the consumer shall have and use an accurate temperature-indicating device to check for compliance with the temperature requirements in these rules.

(2) All air-packaged smoked fish shall be processed so that the content in the fish of water phase salt is not less than 3%. The determination of salt and moisture content shall be made using the loin muscles of the fish. An operator shall chemically analyze the finished fish product with sufficient frequency using an official method to ensure that the required level of water phase salt is achieved. If a sample of the operator's smoked fish has been analyzed by the department and has been found not to contain the required levels of an ingredient, including water phase salt, then the director of the department may require

additional analyses to be conducted by the operator. The results of the analyses shall immediately be made available to the director of the department upon request.

History: 1997 MR 2, Eff. Feb. 21, 1997.

R 285.569.9 Segregated packaging, handling, and storage area.

Rule 9. Smoked fish product packaging, handling, and storage areas shall be established that are sufficiently segregated within the facility apart from unprocessed fish and equipment, objects, and employees who have come into contact with waste, raw product, or other unsanitary objects. Packaging material, equipment, employees, and in-process materials that enter product packaging, handling, and storage areas shall be treated so as to minimize the risk of introducing microorganisms. Air handling systems shall be designed to minimize the risk of airborne contamination into product packaging, handling, and storage areas and to provide positive air pressure relative to the surrounding areas.

History: 1997 MR 2, Eff. Feb. 21, 1997.

R 285.569.10 Packaging and labeling.

Rule 10. (1) Every package, carton, wrapper, or other container used to ship, wrap, or hold unfrozen smoked fish in any way at any time, including the packages sold from a bulk display and wrapped at the time of sale, shall be labeled to indicate all of the following information:

(a) The name of the article of food.

(b) The name and address of the manufacturer, packer, distributor, or retailer. If the smoked fish product is not manufactured by the person whose name appears on the label, then the name shall be qualified by a phrase that reveals the connection the person has with the commodity.

(c) The ingredients and net weight, as required by Act No. 39 of the Public Acts of 1968, as amended, and Act No. 283 of the Public Acts of 1964, as amended, being §289.701 et seq. and §290.601 et seq., respectively, of the Michigan Compiled Laws.

(d) The lot code number that identifies the period when processed and packaged, as required in R 285.569.7.

(e) The warning statement: "Perishable—Keep under refrigeration at 38 degrees Fahrenheit (3.3 degrees Celsius) or below."

(f) The warning statement: "Not to be sold or consumed after _____," the blank to be filled with a date, including the month, day, and year. The date shall be not more than 14 days after date of smoking unless an operator can demonstrate to the director of the department that a longer period of time can be achieved that is safe. The director of the department may grant approval for an operator to use a date greater than 14 days, but may invoke at any time, the requirements of R 285.569.14 and R 285.569.15.

(2) The labeling requirements for frozen smoked fish shall be the same as for unfrozen smoked fish, except for the requirements specified in subrule (1)(e) and (f) of this rule. The statements specified in subrule (1)(e) and (f) shall be replaced with the warning statements of this rate: "Perishable: Keep frozen. Thaw in refrigerator before consumption."

(3) All label statements shall appear in a distinctive and plain manner in English words and Arabic numerals. All statements shall be permanently affixed to each separate and distinct package or container.

(4) Smoked fish processed on different dates shall not be commingled in the same container at the processing plant or while the fish is being stored, distributed, or offered for sale.

History: 1997 MR 2, Eff. Feb. 21, 1997.

R 285.569.11 Wholesale sale.

Rule 11. If fish product is sold other than at retail, then all of the following provisions apply:

- (a) All sales shall be accompanied by an invoice or record of sale.
- (b) Each invoice shall include the lot number, expiration date, and warning statement as required in R 285.569.10.
- (c) Copies of all invoices or other adequate records shall be maintained to identify consignments or distributions of designated coded lots.

History: 1997 MR 2, Eff. Feb. 21, 1997.

R 285.569.12 Sale of fish product under other than original expiration date code prohibited.

Rule 12. Smoked fish product shall not be sold under any expiration date code other than the original expiration date code that the processor assigned to the fish product.

History: 1997 MR 2, Eff. Feb. 21, 1997.

R 285.569.13 Records; availability; time of retention.

Rule 13. All process time and temperature records, temperature device standardization records, and all records of sales required by these rules shall be made available to the director of the department for inspection and copying upon request and shall be retained at the place of business for a period of not less than 6 months.

History: 1997 MR 2, Eff. Feb. 21, 1997.

R 285.569.14 Modifications and waivers.

Rule 14. The director of the department may grant a variance to a petitioner by modifying or waiving the requirements of these rules if the director is shown that the proposed alternative is equally effective in preventing food safety hazards. If a variance is granted, then the director of the department shall retain the information specified in R 285.569.16 as part of the official record. Proprietary information submitted to satisfy a petition for a variance shall not be subject to public disclosure.

History: 1997 MR 2, Eff. Feb. 21, 1997.

R 285.569.15 Documentation of proposed variance and justification.

Rule 15. Before a variance from these rules is approved by the director of the department, the information that is provided by the person requesting the variance shall include all of the following:

- (a) A statement of the proposed variance from the rule requirements that cites the relevant rule numbers.
- (b) An analysis of the rationale for how the potential public health hazards addressed by the relevant rule will be alternatively addressed by the proposal. If not included in the analysis, the director may require, but shall not be limited to requiring, any of the following:
 - (i) A letter from a process authority.
 - (ii) Copies of relevant articles from scientific journals.
 - (iii) Studies obtained or performed consisting of not less than 3 processing tons showing that under the requested parameters the desired result is reliably achieved.
 - (iv) laboratory analyses that demonstrate both of the following:
 - (A) For *Clostridium botulinum* zero toxin production in the fish product through a time period beyond the shelf life of the product of not less than 1/3 of the shelf life, demonstrated through inoculated pack studies under normal and moderate abuse conditions.

- (B) No detectable Listeria monocytogenes in the final fish product.
- (v) Actual federal, state, or local government regulations or advisories.
- (c) A HACCP plan that includes the information specified in R 285.569.17 as it is relevant to the variance requested.
- (d) If the person is a processor outside this state, verification of inspection or licensing by a regulatory agency as an approved source of smoked fish.

History: 1997 MR 2, Eff. Feb. 21, 1997.

R 285.569.16 Operator requirements if variance granted or HACCP plan required; revocation of variance; expiration of variance.

Rule 16. (1) If the director of the department grants a variance or if a HACCP plan is otherwise required, the operator shall comply with all of the following provisions:

(a) Comply with the HACCP plan and procedures that are submitted as a basis for the modification or waiver.

(b) Maintain and provide to the director of the department, upon request, records specified in R 285.569.17 that demonstrate that all of the following are routinely employed:

- (i) Procedures for monitoring critical control points.
- (ii) Monitoring of the critical control points.
- (iii) Verification of the effectiveness of an operation or process.
- (iv) Necessary corrective actions if there is a failure at a critical control point.

(c) Notify the director of the department, in writing, when any change, replacement, or modification to the information required under R 285.569.17 has been made which affects any requirement listed under R 285.569.15.

(2) The director of the department may revoke a variance and may require resubmission of a petition if any inspection, monitoring, analysis, or other official activity conducted by the department or other regulatory agency reveals a condition creating a potential food safety hazard that the petitioner or plans failed to control or address.

(3) The director of the department may set an expiration date for a variance after which a petition may be resubmitted. The petitioner will be notified in writing if an expiration date is set.

History: 1997 MR 2, Eff Feb. 21, 1997.

R 285.569.17 Contents of a HACCP plan.

Rule 17. Where not preempted by federal statute, HACCP plans prepared in accordance with R 285.569.15 Shall specify, for each type of fish product, all of the following information:

(a) The identity of the individual smoked fish product or categorization of like products that the plan addresses.

(b) The potential food safety hazards, such as microbiological, chemical, or physical hazards, that may cause a fish product to be unsafe for human consumption.

(c) A flow diagram that depicts the operator's entire fish processing procedures and identifies each critical control point.

(d) Employee and supervisory training plans that address the food safety issues of concern.

(e) A statement of standard operating procedures for the plan under consideration, including clearly identifying all of the following:

- (i) Each critical control point, including all of the following:
 - (A) Raw material thawing.
 - (B) Brining or dry salting.
 - (C) Smoking.
 - (D) Cooling after smoking.

(E) Post-smoke processing, if any.

(ii) The critical limits that must be met at each critical control point specked in paragraph (i) of this subdivision to prevent unacceptable food safety hazards.

(iii) The method and frequency for monitoring and controlling each critical control point by an employee designated by the operator.

(iv) The method and frequency for the operator to routinely verify that an employee is following standard operating procedures and monitoring critical control points.

(5) The action to be taken by the operator if the critical limits for each critical control point are not met.

(6) The records to be maintained by the operator to demonstrate that the HACCP plan is properly operated and managed.

(f) Additional scientific data or other information required by the director.

History: 1997 MR 2, Eff. Feb. 21, 1997.

R 285.569.18 Processes requiring variance.

Rule 18. All of the following processes require a variance under R 285.569.14:

(a) The production of cold process smoked fish.

(b) Subjecting smoked fish to reduced oxygen packaging.

(c) The use of additives that reduce the level of, combine with, or replace, in whole or in part, the sodium chloride used in the smoked fish product at the required level, such as sodium nitrite, potassium chloride, or any other approved food additive.

History: 1997 MR 2, Eff. Feb. 21, 1997.

R 285.569.19 Rescission.

Rule 19. R 285.541.1 to R 285.541.11 of the Michigan Administrative Code, appearing on pages 1200 to 1202 of the 1979 Michigan Administrative Code, are rescinded.

History: 1997 MR 2, Eff. Feb. 21, 1997.